

**K193549 SIGMA High Performance (HP) Partial Knee System**Apr 16, 2020  
118 days to decisionK193549 · Product code: **HRY** · Orthopedic  
Source: <https://www.510kdatabase.net/k193549/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/polymer (HRY)
Date received	Dec 20, 2019
Decision date	Apr 16, 2020
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Depuy Ireland UC</b>
Location	Ringaskiddy, IE
Contact	Erin Combs
510(k) history	47 submissions · 47 cleared · 2018-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193549/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 15, 2026